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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,169	04/19/2001	Theresa Ann Jeary	P24,622 USA	3922

61214 7590 08/23/2006

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,169	JEARY ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,20,23-34,36-40,45-51 and 55-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,20,23-34,36-40,45-51 and 55-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *08/09/06* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 24, 28-30, 55-58 and 60-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the limitation "the combined amount of said ammonio methacrylate copolymer and said plasticizer in said membrane coating being in an amount of from about 4% to about 15% of the weight of the cores present in said formulation". During the interview dated 08/09/06, applicant's attorney directed the examiner's attention to page 24, and tables 4-5 to show support for the above limitation. However, this rejection is maintained for the following reasons: 1) the 4%, 6%, 8%, 10%, 12% and 15% disclose in page 24 is referring to the percent amount of polymer in the coating; 2) the percent amount of polymer in the coating disclosed in page 24 is the result of the polymer coating composition in table 3, which has no plasticizer; and 3) this limitation is contradicting to the disclosure on pages 12-13, which disclosed that the rate controlling membrane including all solid components such as plasticizer is from about 11% to 450%. The 4%, 6%, 8% and 10% are outside of the

about 11-450% range. Furthermore, table 9 appears to suggest that only formulations having 4%, 6%, 8% levels of polymer coat are enabled because they exhibited potency values over 97%.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 5, 20, 23-34, 36-40, 45-51 and 55-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norling et al. US 5,958,458, in view of Van Balken et al. US 6,183,780.

Norling teaches a pharmaceutical multiparticulate formulation in the form of coated cores (abstract). The core is in the form of pellets, comprising active agent and excipient (columns 2, lines 33-42; and column 13, lines 29-67). The active agent includes antidepressants (column 6, lines 35-40). The coated multiparticulate is formulated into oral solid dosage form including tablet, capsule, powder or granule suitable to release active agent during a 24 hours period (column 13, lines 20-36). Suitable coating polymers includes ethyl cellulose, Eudragit® E, Eudragit® RS or RL, polyvinyl acetate phthalate (columns 9-10).

It is noted that the Norling does not expressly teach the release profiles. However, products of identical chemical composition cannot have mutually exclusive

properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Accordingly, it is the position of the examiner that the release profile is inherent because Norling teaches the use of the same rate control release polymer, *e.g.*, Eudragit® E, Eudragit® RS or RL.

Norling does not explicitly teach fluvoxamine in the composition.

Van Balken teaches an oral delayed immediate release formulation comprising active core coated with rate control release polymer (columns 5-6). The active agent in the core is an antidepressant, *e.g.,* fluvoxamine (column 5, lines 24-25). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify pharmaceutical multi-particulate formulation of Norling using fluvoxamine as an antidepressant in view of the teaching of Van Balken, because the references teach that antidepressant can be incorporated in an extended release formulation, such as coated beads/pellets. The expected result would be a slow/controlled release formulation containing antidepressants drug having prolonged release rate.

It is noted that the Norling does not expressly teach the release profiles as well as the blood serum level. However, products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Where the claimed and prior

art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Accordingly, the burden is shifted to applicant to show that the composition of Norling would not exhibit the claimed properties, because Norling teaches the use of the same rate control release polymer, *e.g.*, Eudragit® E, Eudragit® RS or RL.

Response to Arguments

Applicant's arguments filed 05/31/06 have been fully considered but they are not persuasive.

Applicant argues that Norling teaches ammonio methacrylate copolymer and plasticizer in example 10. However, the total amount of copolymer and plasticizer is 34.2%. In response to applicant's argument, Norling is relied upon for the teachings within the four-wall patent. Norling cannot be limited to his best mode as described in the examples. Furthermore, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Hence, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine suitable amount of coating to obtain the claimed

invention, because Norling teaches the use of the same rate control release polymer, *e.g.*, Eudragit® E, Eudragit® RS or RL, and for the same purpose, namely, a controlled release dosage form suitable for antidepressants.

Applicant argues there is no motivation to combine the references. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both references teach controlled release formulations suitable for antidepressants. Van Balken teaches fluvoxamine as a well-known antidepressant in pharmaceutical art. It is noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Interview Summary

Applicant's attorney proposed amendment to place the application in condition for allowance. The examiner suggested: 1) incorporating claims 4 and 5 into all

independent claims; 2) deleting new matter limitations (see above 112, 1st paragraph rejection); and 3) incorporating limitations with respect to the structure that results in the claimed properties. No agreement was reached.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

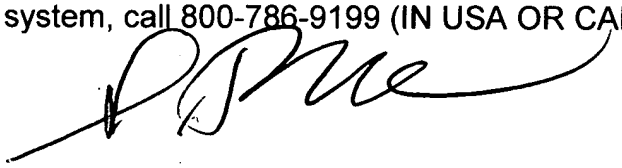
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



S. Tran
Examiner
Art Unit 1615